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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/808,878
Filing Date: March 15, 2001
Appellant(s): PICKAR, JAMES H.

Thomas J. Meloro
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed October 19, 2004.

*(1) Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

*(2) Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existance of any related appeals and interferences.

*(3) Status of Claims*

The statement of the status of the claims contained in the brief is correct.

*(4) Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

*(5) Summary of Invention*

The summary of invention contained in the brief is correct.

*(6) Issues*

The appellant's statement of the issues in the brief is correct.

*(7) Grouping of Claims*

The rejection of claims 7, 11, 12 and 69 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

*(8) Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

*(9) Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent Re. 36,247 Plunkett et al. July 6, 1999

*(10) Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 7, 11, 12 and 69 are rejected under 35 U.S.C. 103(a) over Plunkett et al.

These rejections are fully set forth in prior office action mailed September 10, 2003, and reiterated in full below.

*(11) Response to Argument*

Claims 7, 11, 12 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plunkett et al. (USPN RE 36,247).

Plunkett et al. (USPN RE 36,247) teaches a method of treating hot flashes comprising administering continuously and uninterruptedly both progestogen and estrogen in daily dosage units, see claims 21-34, col. 3, lines 51-59 and co1.8 lines 62-64 in particular. Plunkett et al. (USPN RE 36,247) also teaches conjugated equine estrogen/medroxyprogesterone as one of the estrogen/progestogen combinations useful in its method, see claims 21-34. Plunkett teaches the minimum and maximum dosages for medroxyprogesterone (MPA) and conjugated equine estrogens (CEE) to be 1 mg/day and 15 mg/day, and 0.300 mg/ day and 2.5 mg/day, respectively,

and the preferred dosages are 1-2.5 gm (MPA) and 0.300-0.600 mg (ECC) respectively, see claims 34-35, see also Table IA, col.4, in particular.

Plunkett et al. does not particularly teach the dosages of conjugated equine estrogen/medroxyprogesterone claimed herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ conjugated equine estrogen/medroxyprogesterone in the specific dosages claimed herein in a method of treating hot flashes.

One of ordinary skill in the art would have been motivated to employ conjugated equine estrogen/medroxyprogesterone in the specific dosages claimed herein in a method of treating hot flashes because they (dosages herein) fall within the therapeutic ranges of the conjugated equine estrogen/medroxyprogesterone taught by the prior art. Optimization of amounts is within the purview of the Skilled Artisan, and is therefore obvious absent evidence to the contrary. No such evidence is seen.

Appellants' arguments have been fully considered but they are not persuasive.

***A prima facie case of obviousness have been established.*** Appellants first argue that prima facie case of obviousness has not been established. Particularly, appellants argue "there is nothing in Plunkett to teach or suggest the selection of 1.5 mg MPA for the treatment of vasomotor symptoms in combination with about 0.3 to about 0.45 mg CEE." Note that Plunkett teaches that MPA can be employed at a minimum dosage of 1.0 mg and maximum dosage of 15 mg, and preferred range of 1-2.5 mg/day (claim 32). Note that the claimed dosage herein, 1.5 mg/day, falls within the Plunkett range. Note also that the claimed dosage herein, 0.3-0.45 mg of CEE, falls within the dosage range of Plunkett 0.300-0.600 mg, see claim 35 of Plunkett. It

would have been prima facie obvious to one of ordinary skill in the art to use 1.5 mg/day of MPA and 0.3-0.45 mg/day of CEE because the amounts herein are within the relatively narrow range disclosed in the prior art.

***The objective evidences on the record are not sufficient to overcome the obviousness.*** Appellant draws the examiner's attention to data presented in the specification showing the efficacy of the dosages herein versus that of the "common daily dosages" of Premarin and MPA. Note that in order to overcome obviousness appellants must demonstrate unexpected and significant results in comparison with the closest prior art, i.e., Plunkett. No such comparative data has been provided. Appellants state that the closest example in Plunkett is a regimen comprising 0.600 mg CEE and 2.5 mg MPA. The specification on page 9 provides a comparative example between 60.625 mg of CEE, and not 0.600 mg of CEE. Furthermore, the data presented does not constitute unexpected results because according to appellants' remarks, the data shows similar efficacy of the following regimens: 0.625 CEE/2.5 MPA, 0.45 CEE/1.5 mg MPA, 0.30 CEE/1.5 MPA. Some data points are overlapping in both number and severity of hot flushes. Assuming arguendo that lower dose of MPA and CEE claimed herein yield similar therapeutical results, then the teachings of the prior art is confirmed. Plunkett teaches a wide range of CEE/MPA as effective in treating hot flushes. Therefore, the showing on page 9 of the specification indeed confirms the teachings of the prior art that the entire range disclosed in Plunkett is effective in treating hot flushes.

The two declarations of Dr. Lobo submitted under 37 CFR 1.132 have been fully considered, but are not persuasive to remove the obvious rejection herein. Dr. Lobo asserts that conventional accepted combination treatment of conjugated equine

estrogen/medroxyprogesterone is 0.625 mg/2.5 mg daily, and such amounts have been accepted as the minimum effective amounts. Therefore, the lower dosage (0.3 to 0.54 mg/1.5 mg) as claimed in the application would have not been expected to be effective in view of the conventional accepted dosage.

The assertion is not persuasive. Note the Plunkett et al., a patent issued in the past 20 years contradicts this very proposition since it teaches ranges of CEE/MPA that encompass the dosage claimed herein, with 0.6 mg/2.5 mg as the up limit of the preferred embodiments. The claimed amounts are within the range disclosed in the prior art. It is noted that the range are relatively narrow, and what appellants proved is nothing more than what is expected according the cited prior art. As to the alleged unexpected additive or synergistic effect of MPA and CEE, it is noted that Plunkett et al. particularly teach the combination of MPA/CEE. Further, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). For the above reasons, it is believed that the rejections should be sustained.

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PRIMARY EXAMINER

Respectfully submitted,

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April 1, 2005

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